DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 13, 2015

PHADIA US, INC.
C/O MR. MARTIN R. MANN
SENIOR REGULATORY AFFAIRS MANAGER
4169 COMMERCIAL AVENUE
PORTAGE, MI 49002

Re: k141375
Trade/Device Name: EliA™ M2 Immunoassay
EliA™ M2 Positive Control 100
EliA™ M2 Positive Control 250
Regulation Number: 21 CFR §866.5090
Regulation Name: Antimitochondrial antibody immunological test system
Regulatory Class: Class II
Product Code: DBM
Dated: December 22, 2014
Received: December 24, 2014

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -A

Leonthena Carrington, MS, MBA, MT (ASCP)
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Division of Immunology and Hematology Devices
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141375

Device Name
EliA(TM) M2, EliA(TM) M2 Positive Control 100, EliA M2 Positive Control 250

Indications for Use *(Describe)*
EliA M2 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to M2 in human serum and plasma (heparin, EDTA) to aid in the clinical diagnosis of primary biliary cirrhosis in conjunction with other laboratory and clinical findings. EliA M2 uses the EliA IgG method on the instrument Phadia 100.

EliA M2 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to M2 in human serum and plasma (heparin, EDTA) to aid in the clinical diagnosis of primary biliary cirrhosis in conjunction with other laboratory and clinical findings. EliA M2 uses the EliA IgG method on the instrument Phadia 250.

EliA M2 Positive Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of M2 antibodies with Phadia 100 using the EliA IgG method.

EliA M2 Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of M2 antibodies with Phadia 250 using the EliA IgG method.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

A.7. 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number: K141375

Date of Summary Preparation: February 13, 2015

Manufacturer:
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Device Name:
EliA™ M2 Immunoassay
EliA™ M2 Positive Control 100
EliA™ M2 Positive Control 250

Common Name: Antimitochondrial antibody immunological test system

Classification

Product Name	**Product Code**	**Class**	**CFR**
EliA™ M2	DBM	II	866.5090
EliA™ M2 Positive Control	JJY	I	862.1660

Substantial Equivalence to

Quanta Lite M2 EP (MIT3), INOVA	K052262

Intended Use Statements of the New Devices

1) EliA M2 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to M2 in human serum and plasma (heparin, EDTA) to aid in the clinical diagnosis of primary biliary cirrhosis in conjunction with other laboratory and clinical findings. EliA M2 uses the EliA IgG method on the instruments Phadia 100 and Phadia 250.

2) EliA M2 Positive Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of M2 antibodies with Phadia 100 using the EliA IgG method.

3) EliA M2 Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of M2 antibodies with Phadia 250 using the EliA IgG method.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

Phadia® 100/Phadia® 250 are fully automated immunoassay analyzers, which include software for evaluation of test results.

General Description of the New Device

The new device belongs to a fully integrated and automated system for immunodiagnostic testing. It comprises a Fluorescence-Immunoassay test system using EliA single wells as the solid phase and is intended to be performed on the instruments Phadia 100 and Phadia 250.

The conjugate for the EliA IgG method is mouse anti-human IgG beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate.

The total IgG calibration is based on a set of six WHO-standardized IgG Calibrators derived from human serum. They are used to establish an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-, method-specific and general reagents that are packaged as separate units.

Test Principle of the New Device
The EliA Wells are coated with the following antigens:

Test	Antigen coated to the wells:
EliA M2	Native pyruvate dehydrogenase complex from mitochondria and recombinant M2-antigen

If present in the patient's specimen, antibodies to these proteins bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the more specific IgG is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Device Comparison
The new and the predicate devices both represent non-competitive solid phase ELISAs. The IVDs are used as an aid in the diagnosis of the following diseases:

Disease	Detection of antibodies to
Primary biliary cirrhosis	M2

Laboratory equivalence
The comparability of the predicate devices and new devices is supported by a data set including

- **results obtained within a comparison study between new and predicate device**
- **results obtained for clinically defined sera**
- **results obtained for samples from apparently healthy subjects (normal population).**

In summary, all available data support that the new devices are substantially equivalent to the predicate devices.